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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,345	08/01/2003	Victor Selig	ST8630US	3729
22203	7590	04/06/2006	EXAMINER	
KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143			JOHNSON, EDWARD M	
			ART UNIT	PAPER NUMBER
			1754	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/633,345

**Applicant(s)**

SELIG ET AL.

**Examiner**

Edward M. Johnson

**Art Unit**

1754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/03,8/04,9/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the legal term "means" is used in line 9. Correction is required.

See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 10, "said circulation systems" lacks antecedent basis. Examiner suggests --said circulation system--.

Claim 2, "said deactivated items therein" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Halstead et al. US 6,919,057.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any

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invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 4, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

- a) placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),
- b) placing the container into a reprocessor (abstract),
- c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),
- d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed.

When the examiner has reason to believe that the functional language asserted to be critical for establishing novelty in claimed subject matter may in fact be an inherent characteristic of the prior art, the burden of proof is shifted to Applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied upon. In re Fitzgerald et al. 205 USPQ 594. As a practical matter, the Office is not equipped to manufacture or obtain products and make resulting comparisons

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with the claimed invention. Where, as here, the burden has been shifted to applicant, it is appropriate to make a rejection based upon §102 as well as §103.

Regarding claim 5, Halstead '057 discloses liquid (abstract).

Regarding claim 6, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead '057.

Regarding claim 1, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor,

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Halstead fails to disclose causing the container to assume the closed position at removal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close to container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed.

Regarding claim 2, Halstead '057 discloses removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Regarding claim 3, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

#### **Conclusion**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Oberleitner et

al. US 6,068,815 discloses a method for reprocessing an endoscope comprising transferring sterilants by pneumatic force (see abstract and Examples).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M. Johnson whose telephone number is 571-272-1352. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

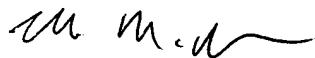


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Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "E. M. Johnson", with a stylized flourish at the end.

Edward M. Johnson  
Primary Examiner  
Art Unit 1754

EMJ